

PATIENT GROUP DIRECTION (PGD)

**Administration of PRILOCAINE HYDROCHLORIDE 30MG/ML with
FELYPRESSIN 0.03UNITS/ML .**

**1st line - Citanest 3% with Octapressin® = UK licensed product .
2nd line – Xylonest 3% with Octapressin® = imported product used
only when the UK product unavailable**

**By Clinical Nurse Specialist in colposcopy/hysteroscopy clinic at
Royal Derby Hospital**

Documentation details

Reference no:	UHDB154
Version no:	1
Valid from:	11/05/2022
Review date:	11/11/2024
Expiry date:	10/05/2025

Change history

Version number	Change details	Date
V1	New template	23/3/22

Glossary

Abbreviation	Definition

1. PGD template development (PGD Working Group)

PGD Working Group Membership (minimum requirement of consultant, pharmacist and a registered professional who can work under a PGD, or manages the staff who do). If this is a review of existing PGD, replace previous names with the individuals involved for this version

Name	Designation
Mr O Tamizian	Lead Colposcopist
Miss S Kolhe	Lead Hysteroscopist
Mrs G Lowe	Lead Nurse Colposcopist
Mr D Casayuran	Nurse Hysteroscopist
S Dumbleton	Women and Children's Lead Pharmacist

Where an antimicrobial is included, confirm the name, designation and date of the antimicrobial pharmacist who has reviewed this version

Name of antimicrobial pharmacist	Designation	Date Reviewed
N/A		

2. Organisational authorisations

The PGD is not legally valid until it has had the relevant organisational authorisation.

University Hospitals of Derby & Burton NHS Foundation Trust authorises this PGD for use by the services or providers listed below:

Authorised for use by the following organisation and/or services
Colposcopy and Hysteroscopy Department within Gynaecology Out Patients department at Royal Derby Hospital
Limitations to authorisation
The professionals to which this protocol applies are the clinical nurse specialist in colposcopy and hysteroscopy.

Organisational Authorisation (legal requirement).			
Role	Name	Sign	Date
Medicines Safety Officer	James Hooley	Signed copy held by Pharmacy	11/05/2022

Additional signatories (required as per legislation and locally agreed policy)			
Role	Name	Sign	Date
Women's and Children's Lead Pharmacist	Susi Dumbleton	Signed copy held by Pharmacy	29/03/2022
Lead Colposcopist	Onnig Tamizian	Signed copy held by Pharmacy	24/03/2022
Lead Hysteroscopist	Shilpa Kolhe	Signed copy held by Pharmacy	03/05/2022
Clinical nurse Specialist in colposcopy	Gaynor Lowe	Signed copy held by Pharmacy	25/03/2022
Clinical nurse Specialist in hysteroscopy	Dennis Casayuran	Signed copy held by Pharmacy	24/03/2022

Local enquiries regarding the use of this PGD may be directed to UHDB.PGDgovernance@nhs.net

Section 7 provides a registered health professional authorisation sheet. Individual professionals must be authorised by name to work to this PGD.

3. Characteristics of staff

Qualifications and professional registration	Registered nurse with a current NMC registration
Initial training	<ul style="list-style-type: none"> • Completion of all Essential-to-role training as outlined in the UHDB PGD policy. • Individual has read and understood full content of this PGD and signed authorisation (section 7) • Completion of Medicines Management Drug Assessment • Trained according to the British Society of Colposcopy and Cervical Pathology guidelines or has completed nurse hysteroscopist training • Has undertaken appropriate training to carry out clinical assessment of patient leading to diagnosis that requires treatment according to the indications listed in the PGD.
Competency assessment	<p>Approved drug assessment</p> <p>Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions</p> <p>Individuals operating under this PGD are personally responsible for ensuring they remain up to date with the use of all medicines included in the PGD - if any training needs are identified these should be discussed with either authorising manager (section 7) or the manager within the PGD working group (section 1) so that further training can be provided as required.</p>
Ongoing training and competency	<p>Annual Medicines Safety Training (essential to role)</p> <p>Review/repeat initial training above when this PGD is revised</p> <p>It is the responsibility of the individual registered nurse to remain updated, with evidence of continued professional development in relation to colposcopy services including annual mandatory training in CPR/life support/anaphylaxis competences, with evidence of updates as required.</p>
<p><i>The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisation policies.</i></p>	

4. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	<p>Used during a colposcopy procedure when the cervix requires treatment or during cervical biopsy. Used for local anaesthesia to infiltrate the cervix prior to a large loop excision of the transformation zone.</p> <p>During hysteroscopy for treatment of cervical stenosis or as local anaesthetic for fitting of levonorgestrel IUD (Mirena®)</p>
Criteria for inclusion	Patients over 16 years requiring a colposcopy and hysteroscopy
Criteria for exclusion	<ul style="list-style-type: none"> • Previous sensitivity or intolerance to anaesthetics of the amide type or any other component of the solution • patients under 16 years • patients with anaemia or congenital or acquired methaemoglobinaemia <p>Hysteroscopy only:</p> <ul style="list-style-type: none"> • pregnancy • inflammation or infection
Cautions including any relevant action to be taken	Cardiovascular disease, hypovolaemia, shock, impaired respiratory function, epilepsy, myasthenia gravis, severe hypertension or cardiac arrhythmias.
Action to be taken if the patient is excluded	Refer to medical staff for review and prescribing of alternative agent if appropriate. Document reason for exclusion in patient case notes.
Action to be taken if the patient or carer declines treatment	Document refusal, action taken and advice given in nursing documentation and refer to medical staff if appropriate.
Arrangements for referral for medical advice	Colposcopy and Hysteroscopy clinics are undertaken under consultant lead and the nurse specialist may contact them directly for support.

5. Description of treatment

Name, strength & formulation of drug	Prilocaine hydrochloride 30mg/ml with felypressin 0.03 units/ml
Legal category	POM
Route / method of administration	Local infiltration anaesthesia
Indicate any off-label use (if relevant)	Best practice advice given by BSCCP is used for this PGD and may vary from the manufacturer's summary of product characteristics.
Dose and frequency of administration	<p>Citanest with Octapressin® (prilocaine 30mg/ml with felypressin 0.03units/ml).</p> <p>Initial dose - Infiltrate each third/quarter of the cervix with 2.2mls to a</p>

	<p>depth of ¼inch. Usual total dose used is 6.6mls-8.8mls.</p> <p>IF USING IMPORT: <u>Xylonest with Octapressin (prilocaine 30mg/ml with felypressin 0.03units/ml).</u> Initial dose - Infiltrate each quarter of the cervix with 1.8mls to a depth of ¼ inch. Usual total dose used is 7.2mls.</p>
Duration of treatment	Throughout duration of procedure up to the maximum dose outlined above.
Quantity to be supplied (leave blank if PGD is administration ONLY)	N/A
Storage	Stock must be securely stored according to UHDB medicines policy and in conditions in line with SPC as detailed below: Store in a locked medicines cupboard.
Drug interactions	<p>Patients receiving concomitant therapy with sulphonamides e.g.cotrimoxazole are at increased risk of developing methaemoglobinaemia.</p> <p>If the patient is receiving any concomitant medication or treatment it is the responsibility of the person identified in “Staff Group” to ensure that treatment with the drug detailed in this direction is appropriate. Check all concurrent medication with the patient and in the current BNF before supplying. Refer to a doctor if the patient is taking any medication that may interact with the intended treatment. If in any doubt advice should be sought and recorded before the drug is administered.</p>
Adverse reactions	Systemic side effects are rare with this preparation but may occur if inadvertent intravascular injection occurs. Monitor for CNS side-effects such as lightheadedness, drowsiness, numbness of tongue/mouth, restlessness, tingling/paraesthesias, blurred vision, twitching, tremor or convulsion.
Management of and reporting procedure for adverse reactions	<ul style="list-style-type: none"> • Consult medical advice if an adverse event occurs • Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: https://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient’s medical record. • Serious adverse reactions (moderate harm or above as per NRLS definition) should be reported via trust incident management system (e.g. Datix) to ensure duty of candour and learning from harm during clinical use. • Resuscitation equipment must be available with adrenaline in the event of anaphylaxis – contact resuscitation team on 2222 if occurs)
Written information to be given to patient or carer	Not applicable
Patient advice / follow up	Monitor for sensitivity reactions;

treatment	<p>Verbal advice on why drug administered, action of the drug and subsequent management of condition</p> <p>The individual/carer should be advised to seek medical advice in the event of an adverse reaction.</p>
Records	<p>The Clinical nurse specialist working under the PGD, must capture/document all of the following in the patient case notes and IT system:</p> <ul style="list-style-type: none"> • name of individual, address, date of birth and GP with whom the individual is registered (if relevant) • name of registered health professional • name of medication supplied/administered • date of supply/administration • dose, form and route of supply/administration • quantity supplied/administered • batch number and expiry date (if applicable e.g. injections and implants) • advice given, including advice given if excluded or declines treatment • details of any adverse drug reactions and actions taken • Confirm whether <u>supplied and/or administered</u> and that this was done via Patient Group Direction (PGD) <p>Records should be signed and dated (or a password controlled e-records).</p> <p>All records should be clear, legible and contemporaneous.</p>

6. Key references

Key references	<ul style="list-style-type: none"> • <i>Prilocaine hydrochloride 3% w/v with felypressin 0.54micrograms/ml, summary of product characteristics</i>, https://mhraproducts4853.blob.core.windows.net/docs/b041d90a570d3f8af73ca52cdc6de1a4f51167f1 accessed 01/02/22 • <i>Prilocaine hydrochloride 3% w/v with felypressin 0.54micrograms/ml, patient information leaflet</i>, https://mhraproducts4853.blob.core.windows.net/docs/082fdde89f0e22da37ea87f014e44c6c17b1cf13 accessed 01/02/22 • <i>NICE Medicines practice guideline "Patient Group Directions"</i> https://www.nice.org.uk/guidance/mpg2 • <i>British Society for Colposcopy and Cervical Pathology; Colposcopy Practice Statement, 2017</i>, https://www.bsccp.org.uk/assets/file/uploads/resources/BSCCP_Local Anaesthetic Statement 09.05.17.pdf , accessed 25/01/22
-----------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

7. Registered health professional authorisation sheet

PGD Name [version]: Colposcopy/ Hysteroscopy Gynae Outpatient – Prilocaine Hydrochloride with Felypressin - [v1]
PGD ref: UHDB154
Valid from: 11/05/2022 Expiry date: 10/05/2025

Before signing check that the document you have read is published on Koha or is an in-date hard-copy with all necessary authorisations signed in section 2. The Name/Version/Ref of the document you have read **MUST** match this authorisation form.

Registered health professional

By signing this patient group direction you are indicating that

- a) You agree to and understand all content and commit to only work within this framework.
- b) You have completed any core PGD e-Learning or training records on My Learning Passport or within your department.
- c) You meet the staff characteristics and have completed any additional learning/competency outlined in Section 3 of this PGD.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	Designation	Signature	Date

Authorising manager / Assessor

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of University Hospitals of Derby & Burton NHS Foundation Trust for the above named health care professionals who have signed the PGD to work under it.			
Name	Designation	Signature	Date

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.

This authorisation sheet must be retained by a manager in the clinical department where the PGD is in-use to serve as a record of those registered health professionals authorised to work under this PGD.